DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

94583d

San Francisco District
1431 Harbor Bay Parkway
Alameda, CA 94502-7070
Telephone: 510/337-6700

VIA FEDERAL EXPRESS
Our Reference: 3004187317

March 3, 2004

Ping L. Kwan, Owner
Wing Kee Foodstuff Co.
717 Vallejo Street
San Francisco, California 94133

WARNING LETTER

Dear Mr. Kwan:

The U.S. Food and Drug Administration (FDA) conducted an inspection of your facility located at 717 Vallejo Street, San Francisco, CA on November 4, 5, 6, 7 and 28, 2003. The inspection revealed numerous deviations from the Good Manufacturing Practice regulations, Title 21 Code of Federal Regulations, Part 110 (21 CFR 110). At the conclusion of the inspection you were issued a Form FDA 483 (copy attached) which delineated a number of gross insanitary conditions present in your facility at the time of that inspection. These conditions cause the products stored in your facility to be adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act), in that they were prepared, packed, or held under insanitary conditions whereby they may have become contaminated with filth.

The insanitary conditions observed by the FDA investigator are as follows:

1. Your firm failed to take effective measures to exclude pests from the storage facility and to protect against the contamination of food on the premises by pests (21 CFR 110.35(c)). FDA observed rodent activity on and near food products, as follows:

    a. In a lot of [redacted] located in the northwest area of storage room #1, one bag bore mammalian urine stains and a rodent excreta pellet. We acknowledge that you voluntarily destroyed this lot of product.

    b. In a lot of [redacted] located in the southwest closet of storage room #1, two bags were rodent-gnawed, two bags bore mammalian urine stains, one bag bore three rat or mouse hairs,

one bag bore one rodent pellet and another bag bore two rodent pellets. We acknowledge that you voluntarily destroyed this lot of product.

c. In a lot of [redacted] burlap bags of shelled peanuts, located in the western and middle areas of storage room #1, three bags bore rodent excreta pellets and three bags were rodent-gnawed. We acknowledge that you voluntarily destroyed this lot of product.

d. In a lot of [redacted] bags of yellow soybeans, located in the eastern and middle areas of storage room #1, three bags were found to bear mammalian urine stains. We acknowledge that you destroyed this lot of product.

e. A bag of natural black sesame seeds, located in the southeast area of storage room #1, bore mammalian urine stains. We acknowledge that you destroyed this bag of product.

f. Rodent excreta pellets were found in various areas near product bags in storage room #2, specifically the southwest area, the southeast area, and the middle of the room, on November 6, 2003.

g. Rodent excreta pellets were found in various areas of storage room #1, specifically the northwest area, the southwest area, and the middle of the room, on November 6, 2003.

2. Your firm failed to provide sufficient space for storage of materials as is necessary for the maintenance of sanitary operations (21 CFR 110.20(b)(1)). Specifically,

   a. FDA observed several cartons of food in close proximity to the walls of storage room #1.

   b. FDA observed several cartons of food in direct contact with the floor of storage room #1.

At the conclusion of the inspection, the deviations were listed on Form FDA 483 and discussed with you. A copy of this form is enclosed for your ready reference. This list is not meant to be an all-inclusive list of violations. You are responsible for ensuring that your facility operates in compliance with the Act and the Good Manufacturing Practice regulations (21 CFR 110).

We may take further action if you do not promptly correct these violations. For instance, we may take further action to seize your products and/or enjoin your firm from operating. Please respond in writing within fifteen (15) working days of receipt of this letter. Your response should outline the specific things you are doing to correct these deviations. If

you cannot complete all corrections before you respond, we expect that you will explain the reason for your delay and state when you will correct any remaining deviations.

Please send your reply to: Ms. Harumi Kishida, Compliance Officer, U.S. Food and Drug Administration, 1431 Harbor Bay Parkway, Alameda, CA 94502-7070. If you have any questions regarding any issue in this letter, please contact Ms. Kishida at (510) 337-6824.

Sincerely,

Celeste M. Corcoran

Celeste M. Corcoran
Acting District Director
San Francisco District

Enclosure:
Form FDA 483